1 DONALD F. ZIMMER, JR. (State Bar No. 112279) KRISTA L. COSNER (State Bar No. 213338) 2 DRINKER BIDDLE & REATH LLP 50 Fremont Street, 20th Floor 3 San Francisco, California 94105 Telephone: (415) 591-7500 Facsimile: (415) 591-7510 4 Attorneys for Defendant SMITHKLINE BEECHAM CORPORATION dba 6 GLAXOSMITHKLINE 8 UNITED STATES DISTRICT COURT 9 NORTHERN DISTRICT OF CALIFORNIA 10 SAN FRANCISCO DIVISION 11 Case No. CV-08-01598 BZ MARTHA ARRIOLA, 12 Plaintiff, AMENDED AND CORRECTED 13 NOTICE OF REMOVAL AND REMOVAL ACTION UNDER 28 U.S.C. 14 § 1441(B) (DIVERSITY) and 28 U.S.C. § 1441(C) (FEDERAL QUESTION) OF DEFENDANT SMITHKLINE SMITHKLINE BEECHAM 15 CORPORATION dba **BEECHAM CORPORATION dba** GLAXOSMITHKLINE; McKESSON 16 CORPORATION; and DOES 1 through 15, GLAXOSMITHKLINE inclusive. 17 Defendants. 18 19 20 TO THE CLERK OF THE COURT: 21 Defendant SMITHKLINE BEECHAM CORPORATION dba 22 GLAXOSMITHKLINE ("GSK"), hereby submits its Amended and Corrected Notice of 23 Removal and Removal, whereby it removes to this court the state court action described 24 below. At the time of the filing of the original Notice of Removal and Removal, GSK's 25 information indicated that defendant McKESSON CORPORATION ("McKesson") had 26 not yet been served with the Complaint; however, GSK has since learned that McKesson

was served prior to the original removal. Accordingly, GSK now files this Amended and

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Corrected Notice of Removal and Removal.

## Removal is warranted under 28 U.S.C. § 1441 because this is an action over which this Court has original jurisdiction under 28 U.S.C. §§ 1331 and 1332.

I. <u>BACKGROUND</u>

- 1. On March 17, 2008, Plaintiff Martha Arriola ("Plaintiff"), represented by Hersh & Hersh of San Francisco, California, commenced this action in the Superior Court of the State of California for the County of San Francisco. A true and correct copy of the Complaint in the action is attached as Exhibit "A" to the Declaration of Krista L. Cosner in Support of Amended and Corrected Notice of Removal and Removal Action under 28 U.S.C. § 1441(b) (Diversity) and 28 U.S.C. § 1441(c) (Federal Question) of Defendant SmithKline Beecham Corporation dba GlaxoSmithKline (hereinafter "Cosner Decl.").
- 2. Defendant McKesson was served with Plaintiff's Complaint on March 17, 2008. Defendant GSK has not yet been served. Cosner Decl. ¶¶ 9-10.
- 3. Defendant GSK filed its answer to the Plaintiff's Complaint on March 21, 2008. A true and correct copy of the Answer in the action is attached as Exhibit "B" to Cosner Decl. Defendant GSK filed its initial Notice of Removal and Removal on March 24, 2008. There have been no additional proceedings in the state court action. Cosner Decl. ¶ 3.
- 4. This is one of many cases that have been filed recently in both federal and state court across the country involving the prescription drug Avandia®. Cosner Decl. ¶ 6.
- 5. On October 16, 2007, the Judicial Panel on Multidistrict Litigation ("JPML") issued an order directing that then-pending Avandia-related cases be transferred and coordinated for pretrial proceedings in the United States District Court for the Eastern District of Pennsylvania, before the Honorable Cynthia M. Rufe, pursuant to 28 U.S.C. § 1407. See Transfer Order, In re Avandia Marketing, Sales Practices and Products Liability Litigation, MDL 1871 (E.D. Pa.) (a true and correct copy of which is attached as Exhibit "C" to Cosner Decl.). Additional Avandia-related cases pending in

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federal court, which are common to the actions previously transferred to the Eastern
District of Pennsylvania and assigned to Judge Rufe, are treated as potential tag-along
actions. See id.; see also Rules 7.4 and 7.5, R.P.J.P.M.L. 199 F.R.D. 425, 435-36 (2001).
GSK intends to seek the transfer of this action to that Multidistrict Litigation, In re
Avandia Marketing, Sales Practices and Products Liability Litigation, MDL 1871, and
shortly will provide the JPML with notice of this action pursuant to the procedure for
"tag along" actions set forth in the rules of the JPML. Cosner Decl. ¶ 7.

6. As more fully set forth below, this case is properly removed to this Court pursuant to 28 U.S.C. § 1441 because GSK has satisfied the procedural requirements for removal and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1332.

#### II. <u>DIVERSITY JURISDICTION</u>

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because this is a civil action in which the amount in controversy exceeds the sum of \$75,000, exclusive of costs and interest, and is between citizens of different states.

#### A. <u>Diversity Of Citizenship</u>

- 8. Plaintiff, Martha Arriola alleges she is a resident of the State of Nevada. Accordingly, she is a citizen of the State of Nevada. *See* Cosner Decl., Exh. A, ¶ 2.
- 9. GSK is, and was at the time Plaintiff commenced this action, a corporation organized under the laws of the Commonwealth of Pennsylvania with its principal place of business in Philadelphia, Pennsylvania, and therefore, is a citizen of Pennsylvania for purposes of determining diversity. 28 U.S.C. § 1332(c)(1). Cosner Decl. ¶ 8.
- 10. The remaining named defendant, McKesson, is a Delaware corporation with its principal place of business in San Francisco, California, and therefore is a citizen of California. *See* Declaration of Greg Yonko In Support of Defendant's Notice of Removal and Removal Action Under 28 U.S.C. § 1441 (b) (Diversity) and 28 U.S.C. § 1441(c) (Federal Question) in *F.C. Mitchell, et al. v. GlaxoSmithKline, et al.*, ¶ 3, attached as Exhibit "D" to Cosner Decl.

- 11. Accordingly, there is complete diversity of citizenship between Plaintiff and defendants.
- 12. As explained in detail below, McKesson is fraudulently joined in this lawsuit and its citizenship must be ignored for the purpose of determining the propriety of removal. See McCabe v. General Foods, 811 F.2d 1336, 1339 (9th Cir. 1987). Accordingly, the forum defendant rule is not implicated in this case.
- 13. Even if McKesson were not fraudulently joined, there would be complete diversity between Plaintiff and defendants, and McKesson's California citizenship would not affect this Court's jurisdiction. *See Lively v. Wild Oats Markets, Inc.*, 456 F.3d 933 (9th Cir. 2006) (holding that the forum defendant rule limitation on diversity-based removal jurisdiction is a procedural, or non-jurisdictional, rule).

#### B. The Amount In Controversy Requirement Is Satisfied

- 14. It is apparent on the face of the Complaint that Plaintiff seeks an amount in controversy in excess of \$75,000, exclusive of costs and interest.
- 15. Plaintiff alleges that, as a result of her Avandia use, she "suffered chest pain and stroke resulting in permanent damage to her vision." See Cosner Decl., Exh. A, ¶ 27.
- 16. Plaintiff seeks to recover general damages; medical, hospital, and incidental expenses; amounts for loss of earnings and loss of earning capacity, as well as punitive and exemplary damages. *See* Cosner Decl., Exh. A, Prayer for Relief.
- 17. Punitive damages are included in the calculation of the amount in controversy. See Bell v. Preferred Life Assurance Society, 320 U.S. 238, 240 (1943).
- 18. Given the allegations set forth above, the face of the Complaint makes clear that Plaintiff seeks an excess of \$75,000, exclusive of interest and costs. *See Simmons v. PCR Tech.*, 209 F. Supp. 2d 1029, 1031 (N.D. Cal. 2002).

## C. The Citizenship Of McKesson Must Be Ignored Because McKesson Is Fraudulently Joined

19. A defendant is fraudulently joined, and its presence in the lawsuit is ignored for purposes of determining the propriety of removal, "if the plaintiff fails to

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state a cause of action against the resident defendant, and the failure is obvious according
to the settled rules of the state." Morris v. Princess Cruises, Inc., 236 F.3d 1061, 1067
(9th Cir. 2001); see also Hamilton Materials, Inc. v. Dow Chemical Corporation, 494
F.3d. 1203, 1206, 2007 WL 2080179 at *1 (9th Cir. 2007).

- 20. McKesson is fraudulently joined because Plaintiff has failed to make any material allegations against it. *See Brown v. Allstate Ins. Co.*, 17 F. Supp. 2d 1134, 1137 (S.D. Cal. 1998) (finding in-state defendants fraudulently joined where "no material allegations against [the in-state defendants] are made").
- 21. In the body of the Complaint, Plaintiff asserts claims of: (1) strict products liability failure to warn; (2) negligence; (3) breach of implied warranty; (4) breach of express warranty; (5) fraud; (6) fraud by concealment; (7) negligent misrepresentation; and (8) violations of the Consumer Legal Remedies Act, Civil Code §1750, et seq. In these allegations, Plaintiff avers that collectively, "Defendants," defectively designed and manufactured Avandia and made misrepresentations about the drug, Cosner Decl., Exh. A, at ¶ 22, 26, 37; failed to adequately and properly test and inspect Avandia, id. at ¶ 33; failed to use reasonable care in the labeling, selling, inspecting, packaging, and displaying of Avandia, id. at ¶ 33; and concealed known risks and failed to provide adequate warnings and labeling, id. at ¶ 26, 54-55.
- 22. With respect to McKesson, Plaintiff's only allegation is that McKesson is, and was, engaged in the business of marketing, distributing, promoting, advertising and selling Avandia...." *Id.* at ¶ 5. Plaintiff cannot cure this deficiency by relying, as she does in the balance of her complaint, on allegations directed towards "Defendants."
- 23. Plaintiff's claims are substantively based on the design and manufacture of Avandia, the adequacy of pre-clinical testing and post-marketing surveillance, failure to warn, fraudulent concealment, and misrepresentation. As a wholesale distributor of Avandia, McKesson played no role whatsoever in its promotion, marketing or advertising. All McKesson did was pass along unopened boxes of Avandia, in unadulterated form, to hospitals and other businesses in the healthcare industry. See

Cosner Decl. Exh. D, ¶¶ 6-7.1

24. Further, based on the "learned intermediary" doctrine, McKesson bore no duty to warn Plaintiff. The "learned intermediary" doctrine, the foundation of prescription drug product liability law, provides that the duty to warn about a drug's risks runs from the manufacturer to the physician (the "learned intermediary"), and then from the physician to the patient. See Brown v. Superior Court (Abbott Labs.), 44 Cal. 3d 1049, 1061-62, n.9 (1988); Carlin v. Superior Court (Upjohn Co.), 13 Cal. 4th 1104, 1116 (1996). It is the physician, and only the physician, who is charged with prescribing the appropriate drug and communicating the relevant risks to the patient. See Brown, 44 Cal. 3d at 1061-62.

25. GSK and the FDA prepared the information to be included with the prescription drug, Avandia, with the FDA having final approval of the information that could be presented. Once the FDA has determined the form and content of the information, it is a violation of federal law to augment the information. See 21 U.S.C. § 331(k) (prohibiting drug manufacturers and distributors from causing the "alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling" of an FDA-approved drug held for sale); Brown v. Superior Court, 44 Cal. 3d 1049, 1069 n.12 (noting that the FDA regulates the testing, manufacturing, and marketing of drugs, including the content of their warning labels). Therefore, any safety and warning information McKesson had about Avandia would have come from GSK in the form of FDA-approved packaging and labeling. McKesson could not change the labeling it was given by GSK as approved by the FDA without violating federal law. No duty can be

Cal. 1979) ("it is well settled that upon allegations of fraudulent joinder...federal courts may look beyond the pleadings to determine if the joinder...is a sham or fraudulent device to prevent removal")); see also

Ritchey v. Upjohn Drug Co., 139 F.3d 1313, 1318-19 (9th Cir. 1998) (evidence may be presented by the

removing party that there is no factual basis for the claims pleaded against the local defendant).

determining whether McKesson is fraudulently joined. Maffei v. Allstate California Ins. Co., 412 F.

Supp. 2d 1049 (E.D. Cal. 2006) ("[t]he court may pierce the pleadings, consider the entire record, and determine the basis of joinder by any means available") (citing Lewis v. Time, Inc., 83 F.R.D. 455 (E.D.

<sup>1</sup> The Declaration of McKesson's representative, Greg Yonko may be considered by the Court in

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found where it requires a party to violate the law to fulfill it.

26. As such, given the lack of a causal connection between the injuries alleged by Plaintiff and McKesson's conduct, as well as the absence of any legal or factual basis for Plaintiff's claims against McKesson, McKesson's joinder is fraudulent and its citizenship should be ignored for purposes of determining the propriety of removal.

#### III. FEDERAL QUESTION JURISDICTION

- 27. This Court has federal question jurisdiction over Plaintiff's claims under 28 U.S.C. § 1331 and the principles set forth in *Grable & Sons Metal Prods.*, *Inc. v. Darue Eng'g & Mfg.*, 125 S. Ct. 2363 (2005).
- 28. As more fully explained below, Plaintiff has made violations of federal law critical elements of several of her claims.

### A. Plaintiff's Claims Require Construction And Application Of The FDCA And Its Implementing Regulations

- 29. Plaintiff's First Cause of Action, "Strict Products Liability Failure to Warn," Second Cause of Action, "Negligence," Fourth Cause of Action, "Breach of Express Warranty," and Seventh Cause of Action, "Negligent Misrepresentation," each require construction and application of the Federal Food, Drug and Cosmetic Act ("FDCA") and implementing federal regulations, which govern approval of prescription drugs and regulate prescription drug manufacturers' public and promotional statements, including all aspects of warnings and labeling. *See* Cosner Decl., Exh. A.
- 30. As a currently-marketed prescription drug, Avandia is subject to extensive regulation by the FDA. The FDCA requires the FDA to ensure that "drugs are safe and effective" for their intended uses, 21 U.S.C. § 393(b)(2)(B), in part by "promptly and officially reviewing clinical research and taking appropriate action on the marketing of regulated products." 21 U.S.C. § 393(b)(1). The Secretary of the FDA has the authority to promulgate regulations to enforce the FDCA, which are codified in the *Code of Federal Regulations*, 21 C.F.R. § 200, et seq. See 21 U.S.C. § 371(a).
  - 31. To accomplish its purpose, the FDA maintains a Center for Drug

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Evaluation and Research (the "CDER"). The CDER regulates pharmaceutical companies' development, testing and research, and manufacture of drugs. The CDER examines data generated by these companies to conduct a risk/benefit analysis and make an approval decision. The CDER also ensures truthful advertising for prescription drugs, in part by approving Package Inserts that properly outline benefit and risk information. Once drugs are marketed, the CDER continues to monitor them for unexpected health risks that may require public notification, a change in labeling, or removal of the product from the market. In short, the CDER evaluates and monitors the effectiveness and safety

of prescription drugs. See http://www.fda.gov/cder/about/faq/default.htm.

- 32. Promotional communications to physicians about Avandia are contained within, and restricted by, warning, labeling, and promotional materials, such as the Package Insert, that are approved and monitored by the FDA to ensure the provision of accurate information about the drug's respective risks and benefits. Under federal regulations, even claims in promotional labeling or advertising must be consistent with approved labeling. 21 C.F.R. § 202.1(e)(4) (2005).
- 33. The FDA's responsibility to regulate prescription drugs sold in the United States, and to enforce laws with respect to such drugs, inclusive of the precise content and format of prescription drug labeling (e.g., the instructions, warning, precautions, adverse reaction information provided by manufacturers, and marketing materials), is plenary and exclusive. See 21 U.S.C. § 301, et seq.
- 34. Plaintiff has made alleged violations of federal law a critical element of her claims. Accordingly, Plaintiff's claims necessarily raise substantial federal questions by requiring the Court to construe and apply the FDCA and its implementing regulations.

#### B. Federal Control Of Drug Labeling and Warning

35. On January 24, 2006, the FDA announced a rule that includes a detailed and emphatic statement of the FDA's intention that its regulation and approval of prescription drug labeling preempt most state law claims related to the adequacy of prescription drug warnings because such claims frustrate "the full objectives of the

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Federal law." See Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) ("FDA believes that under existing preemption principles, FDA approval of labeling under the act. . . . preempts conflicting or contrary State law."); see also In re Bextra and Celebrex Marketing, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006) (Celebrex decision); In re Bextra and Celebrex Marketing, 2006 WL 2472484 (N.D. Cal. Aug. 24, 2006) (Bextra decision).

- 36. Plaintiff alleges that Defendants failed to disclose certain risks of Avandia. See e.g., Cosner Decl., Exh. A,  $\P$  16. This allegation necessarily requires Plaintiff to establish that the FDA, which has exclusive jurisdiction over the labeling of drugs, would have approved the warning the Plaintiff alleges should have been given.
- 37. Accordingly, there is a substantial federal question with respect to whether Plaintiff can claim that GSK violated state law in light of the FDA's control of Avandia's labeling and warning and its position on conflict preemption.

#### C. The Federal Interest In Providing A Forum

- 38. The federal government has a strong interest in having a federal court decide several of the issues in this case. Among these issues are:
  - a. whether any conduct of GSK violated any federal laws or regulations related to the labeling and marketing of Avandia; and
  - b. whether the FDA-approved Avandia label was false and misleading, as alleged by Plaintiff, and whether a state may impose liability on GSK for not providing more information regarding alleged risks, as Plaintiff contends GSK should have done.
- 39. Plaintiff's claims may be vindicated or defeated only by construction of federal statutes and regulations. The availability of a federal forum to protect the important federal interests at issue is therefore consistent with *Grable*, and determination by a federal court of the substantial and disputed federal issues that lie at the heart of this case would not "disturb any congressionally approved balance of federal and state

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#### IV. CONFORMANCE WITH PROCEDURAL REQUIREMENTS

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Cosner Decl. ¶ 10.	Therefore, this	Removal has	been timely	filed. A	See 28 I	J.S.C. §	
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diversity of citizenship, and the present lawsuit may be removed from the Superior Court

of the State of California for the County of San Francisco, and brought before the United

States District Court for the Northern District of California pursuant to 28 U.S.C. §§

This Court has jurisdiction over this matter based on federal question and

McKesson was served with the Plaintiff's Complaint on March 17, 2008.

1446(b).

1331, 1332 and 1441.

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- 42. Since McKesson is fraudulently joined in this action, and the requirements of 28 U.S.C. §§ 1331 and 1332 are met, GSK is entitled to removal under the plain language of 28 U.S.C. § 1441(b),(c).
- 43. Moreover, McKesson's consent to remove is not necessary because it is fraudulently joined. *See e.g., Emrich v. Touche Ross & Co.*, 846 F.2d 1190, 1193 n.1 (9th Cir. 1988).
- 44. The United States District Court for the Northern District of California is the federal judicial district encompassing the Superior Court of the State of California for the County of San Francisco, where this suit was originally filed. Venue therefore is proper in this district under 28 U.S.C. § 1441(a).
- 45. Pursuant to the provisions of 28 U.S.C § 1446(d), GSK will promptly file a copy of this Notice of Removal with the clerk of the Superior Court of the State of California for the County of San Francisco, where this suit was originally filed.
- 46. Defendant reserves the right to amend or supplement this Notice of Removal.

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WHEREFORE, GSK respectfully removes this action from the Superior Court of 1 2 the State of California for the County of San Francisco to the United States District Court 3 for the Northern District of California, pursuant to 28 U.S.C. § 1441. 4 Dated: March 28, 2008 DRINKER BIDDLE & REATH LLP 5 6 /S/ Krista L. Cosner

DONALD F. ZIMMER, JR. KRISTA L. COSNER

Attorneys for Defendant SMITHKLINE BEECHAM CORPORATION dba **GLAXOSMITHKLINE** 

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2.	A true and a	ccurate copy	of the Com	plaint in this	action is	s attached as
Exhibit A.		+	.*			

- 3. A true and accurate copy of the Defendant's Answer to the Complaint ("Answer") in this action is attached as **Exhibit B**. The Complaint and the Answer are the only state court pleadings known to Defendant to have been filed in this action.
- 4. A true and accurate copy of the Judicial Panel on Multidistrict Litigation's ("JPML") Transfer Order, *In re Avandia Marketing, Sales Practices and Products*Liability Litigation, MDL 1871 (E.D.P.A.) is attached as **Exhibit C**.
- 5. The Declaration of Greg Yonko In Support of Defendant's Notice of Removal and Removal Action Under 28 U.S.C. § 1441(b) (Diversity) and 28 U.S.C. § 1441(c) (Federal Question) in *F.C. Mitchell, et al. v. GlaxoSmithKline, et al.* is attached as **Exhibit D**.
- 6. This is one of many cases that have been filed recently in both federal and state courts across the country involving the prescription drug Avandia.
- 7. GSK intends to seek the transfer of this action to that Multidistrict Litigation, *In re Avandia Marketing, Sales Practices and Products Liability Litigation*, MDL 1871, and shortly will provide the JPML with notice of this action pursuant to the procedure for "tag along" actions set forth in the rules of the JPML.
- 8. GSK is, and was at the time plaintiff commenced this action, a corporation organized under the laws of the Commonwealth of Pennsylvania with its principal place of business in Philadelphia, Pennsylvania, and therefore is a citizen of Pennsylvania for purposes of determining diversity.
  - 9. GSK has not been served with the Complaint in this matter.

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10. I have been informed by a representative from McKesson that it was served with the Complaint in this matter on March 17, 2008.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on this 28th day of March, 2008 in San Francisco, California.

/S/ Krista L. Cosner KRISTA L. COSNER

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**EXHIBIT A** 

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	ŀ	HERSH & HERSH, A Professional Corporation	-Dist
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	5	Telephone: (415) 441-5544	
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	. 6	Attorneys for Plaintiff	
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	- 11	MARTHA ARRIOLA, ) CASE NUMBERS 5 - 8 8 - 4 7 3 3	87
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RS ation	13	Plaintiff, ) COMPLAINT FOR DAMAGES AND	)
	H	) DEMAND FOR JURY TRIAL  vs.	
HERSHANDHERSH A Professional Corporation	14	) [PRODUCTS LIABILITY]	
SH	15	SMITHKLINE BEECHAM )	
A P. P.	16	CORPORATION d/b/a  ) 1. Strict Liability-Failure to Warn  GLAXOSMITHKLINE, McKESSON  ) 2. Negligence	
	- 11	CORPORATION and DOES ONE 3. Breach of Implied Warranty	.
i	17	through FIFTEEN, inclusive,  4. Breach of Express Warranty 5. Fraud	
	18	) 6. Fraud by Concealment	
		Defendants. ) 7. Negligent Misrepresentation	
1.,	19	) 8. Violations of the Consumer Legal Remedies Act (Civil Code §1750, et seq.)	] -
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	i -	DEMAND FOR JURY TRIAL	
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	24	Plaintiff herewith requests a trial by jury as to all issues of material fact.	
1	- 11	PARTIES.	
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	26	<b>2.</b> • · · · · · · · · · · · · · · · · · ·	
	27	Plaintiff MARTHA ARRIOLA is, and was, at all relevant times, a resid	lent
	- 11	of Nevada.	
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		COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL	

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Defendant GLAXOSMITHKLINE (GSK) is a corporation with its principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania 19101. GSK makes a variety of prescription drugs including those for Diabetes Mellitus.

Defendant SMITHKLINE BEECHAM CORPORATION is a U.S. CORPORATION d/b/a GLAXOSMITHKLINE in California.

Defendant McKESSON CORPORATION ("McKESSON") is corporation with its principal place of business at One Post Street, San Francisco, California 94104. At all times herein mentioned, Defendant McKESSON is, and was, engaged in the business of marketing, distributing, promoting, advertising and selling AVANDIA nationwide and in the State of California.

Plaintiff does not know the true names of the Defendants, and each of them. sued herein as DOES ONE through FIFTEEN, inclusive. Plaintiff alleges that each of the fictitiously named Defendants is responsible in some manner for the occurrences herein alleged, and caused the injuries and damages sustained by Plaintiff as herein alleged.

In engaging in the conduct alleged herein, each Defendant acted as the agent for each of the other Defendants.

Defendants SmithKlineBeecham, GlaxoSmithKline, Inc., McKesson and DOES ONE through FIFTEEN, inclusive, will hereafter be referred to as "Defendants".

At all times relevant to this action, Defendants, and each of them, intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of AVANDIA and advertised,

HERSHANDHERSH
A Professional Corporation

promoted, marketed, sold and distributed AVANDIA as a safe pharmaceutical when, in fact, Defendants, and each of them, knew that AVANDIA were not safe for its intended purposes and that AVANDIA would cause, and did cause, serious medical problems, and in some patients, serious, permanent heart injury.

10.

At all relevant times herein, Defendants, and each of them, at all times relevant herein, designed, developed, manufactured, promoted, marketed, distributed, tested, warranted and sold in interstate commerce (including California) AVANDIA. Defendant McKesson has its principal place of business in San Francisco, California, and all said Defendants, and each of them, do substantial business in the State of California, advertise in California, receive substantial compensation and profits from sales of AVANDIA in California.

#### **FACTUAL ALLEGATIONS**

In May 1999, Defendants, and each of them, sought and obtained Food and Drug Administration ("FDA") approval to market a drug manufactured, designed, distributed and sold by Defendants, and each of them, to diabetics purported to increase insulin sensitivity without causing serious effects, harm or injury.

12.

Defendants, and each of them, as a result of strenuous marketing of said drug, AVANDIA, were able to capture a significant share of the market and generate billions of dollars in income and profit as a consequence.

13.

Defendants, and each of them, have continued to reap substantial profits from said drug, AVANDIA, from May of 1999 to the present. By at least September 2005, Defendants, and each of them, knew, but had not disclosed, evidence from studies conducted fro 1999 through 2005 that demonstrated adverse cardiac events in consumers attributable to the drug. Although Defendants, and each of them, had an analysis of 42

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patient studies of AVANDIA it failed to disclose the full results of the study to the FDA, doctors, and patients. The complete results of the study were not provided to the FDA for another year.

14.

During the year 2006, after the time the Defendants, and each of them, were aware of the study results, Defendants, and each of them, increased their sales of AVANDIA to a distribution of approximately 13 (thirteen) million prescriptions in the United States. By way of example in 2006 a month's supply of AVANDIA cost between \$90 and \$200. Thereby Defendants, and each of them, were able to generate sales of \$2.2 billion of this drug in 2006.

At all relevant times herein, AVANDIA was widely advertised by the Defendants, and each of them, as an effective and safe treatment for diabetic patients. Said Defendants, and each of them, minimized the risks posed to diabetic patients by ingestion of AVANDIA. In August 2006, for the first time and as a result of external pressure, Defendants, and each of them, disclosed full and complete results of the study (as in paragraph 15 above) even though the Defendants, and each of them, were fully aware at least since September 2005 of adverse cardiac events due to the drug AVANDIA. Said Defendants, and each of them, concealed or minimized the known risks to diabetic patients by ingestion of AVANDIA.

16.

In doing so the Defendants, and each of them, concealed the known risks to diabetic patients and failed to warn of known and/or scientifically knowable dangers and risks associated with ingestion of AVANDIA.

Plaintiff MARTHA ARRIOLA was prescribed and took AVANDIA commencing in 2000 and continuing through April 2007. As set above in paragraph 15 the Defendants, and each of them, knew that the product was unsafe for diabetic patients in

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general and capable of causing and did cause adverse cardiac events in exposed patients. In spite of the knowledge of the dangerous characteristics of said drug, and with conscious disregard for the health and safety of the public and of exposed patients who were prescribed and took AVANDIA, Defendants, and each of them, placed said drug on the market intending it to be sold to and used by diabetic patients and knowing that said use would occur.

18.

Defendants, and each of them, continued with their sale of AVANDIA after the preliminary disclosure to the FDA in August 2006. Knowing that its drug caused adverse cardiac events and strokes and that the diabetic patient population was not informed of the dangers, Defendants, and each of them, continued to expand sales of AVANDIA to existing and new patients.

On May 21, 2007, Dr. Steven Nissen, a prominent cardiologist associated with the Cleveland Clinic, published a study in the New England Journal of Medicine with his analysis of the 42 studies conducted since 1999. Dr. Nissen's study disclosed to the public the increased risk of congestive heart failure and heart attack by patients taking AVANDIA, dangers the Defendants, and each of them, had been aware of since at least 2005 and probably before.

MARTHA ARRIOLA, while a resident of Henderson, Nevada, was initially prescribed AVANDIA in tablet form by her Family Practitioner beginning in 2000 and continuing until April 2007 when Defendants, and each of them, had failed to disclose to patients and their physicians the true dangers of adverse cardiac events caused by ingestion of the drug AVANDIA.

21.

At all times relevant herein, Defendants, and each of them, failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on

notice of the dangers and adverse effects caused by ingesting AVANDIA including, without limitation, risk of heart attack, congestive heart failure, and stroke.

AVANDIA as designed, manufactured, distributed, sold and/or supplied by Defendants, and each of them, was defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants', and each of their, knowledge of lack of cardiovascular safety.

Defendants, and each of them, thereby acted with fraud, malice, oppression and a conscious disregard for Plaintiff and the general public's safety, who accordingly requests that the trier of fact, in the exercise of sound discretion, award additional damages for the sake of example and for the purpose of punishing the Defendants, and each of them, for their conduct, in an amount sufficiently large to be an example to others and to deter the Defendants, and each of them, and others from engaging in similar conduct in the future. The aforesaid wrongful conduct was done with the advance knowledge, authorization, and/or ratification of an officer, director, and/or managing agent of Defendants, and each of them.

#### FIRST CAUSE OF ACTION

#### [Strict Product Liability - Failure to Warn]

24.

Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation contained in Paragraphs 1-23, inclusive, of this Complaint.

Defendants, and each of them, manufactured, sold and/or distributed AVANDIA to Plaintiff MARTHA ARRIOLA to be used to increase insulin sensitivity without causing serious effects, harm, or injury.

26.

At all times mentioned herein, AVANDIA was dangerous and presented a

substantial danger to diabetic patients and these risks and dangers were known or knowable at the time of manufacture, sale or distribution to Plaintiff MARTHA ARRIOLA from 2000 through April 2007. Ordinary consumers would not have recognized the potential risks and dangers that AVANDIA posed to cardiac patients because its uses were specifically promoted to improve the health of diabetic patients. The AVANDIA was used in a way reasonably foreseeable to all Defendants, and each of them, by Plaintiff MARTHA ARRIOLA. Defendants, and each of them, failed to provide warnings of such risks and dangers to Plaintiff MARTHA ARRIOLA as described herein.

As a result of the defective dangerous condition of AVANDIA manufactured and/or supplied by the Defendants, and each of them, Plaintiff MARTHA ARRIOLA suffered chest pain and stroke resulting in permanent damage to her vision.

As a result of Plaintiff MARTHA ARRIOLA's ingestion of the defective AVANDIA, Plaintiff MARTHA ARRIOLA was caused to suffer the herein described injuries.

In doing the acts herein described, the Defendants, and each of them, acted with oppression, fraud and malice, and Plaintiff is therefore entitled to punitive damages to deter Defendants, and each of them, and others from engaging in similar conduct in the future. Said wrongful conduct was done with advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of the Defendants, and each of them.

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WHEREFORE, Plaintiff prays for judgment against Defendants, and each of them, as hereinafter set forth.

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#### SECOND CAUSE OF ACTION

#### [Negligence]

31.

Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation contained in Paragraphs 1-30, inclusive, of this Complaint.

32.

Defendants, and each of them, and their representatives were manufacturers and/or distributors of AVANDIA. At all times herein, Defendants, and each of them, had a duty to properly manufacture, compound, test, inspect, package, label, distribute, market, examine, maintain supply, provide proper warnings and prepare for use and sell the aforesaid product.

33

Defendants, and each of them, so negligently and carelessly manufactured, compounded, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied aforesaid product, that it was dangerous and unsafe for the use and purpose for which it was intended, that is, increasing insulin sensitivity without causing serious injury, harm, or effect in Plaintiff and others similarly situated. As a result of the carelessness and negligence of Defendants, Plaintiff MARTHA ARRIOLA ingested the AVANDIA in the manner intended by the manufacturer, and, as a result, Plaintiff suffered the injuries and damages described herein.

34.

WHEREFORE, Plaintiff prays for judgment against Defendants, and each of them, as hereinafter set forth.

#### THIRD CAUSE OF ACTION

[Breach of Implied Warranty]

35.

Plaintiff hereby incorporates by reference, as if fully set forth herein, each

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and every allegation contained in Paragraphs 1-34, inclusive, of this Complaint.

36.

Defendants, and each of them, impliedly warranted that their AVANDIA, which Defendants, and each of them, designed, manufactured, assembled, promoted, sold and distributed to Plaintiff were merchantable and fit and safe for ordinary use. Defendants, and each of them, further impliedly warranted that its AVANDIA was fit for the particular purpose of increasing insulin sensitivity in diabetic patients without causing serious harm, injury or effect.

37.

Defendants' AVANDIA was defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which they were sold, and subjected Plaintiff to severe and permanent injuries. Therefore, Defendants, and each of them, breached the implied warranties of merchantability and fitness for a particular purpose when AVANDIA was sold to Plaintiff, in that the AVANDIA is defective and has failed to increase insulin sensitivity without serious harm in diabetic patients as represented and intended.

38.

As a result of Defendants', and each of their, breach of the implied warranties of merchantability and fitness for a particular purpose, Plaintiff MARTHA ARRIOLA has sustained and will continue to sustain the injuries and damages described herein and is therefore entitled to compensatory damages.

39,

After Plaintiff was made aware her injuries were a result of the aforesaid product, AVANDIA, Defendants, and each of them, had ample and sufficient notice of breach of said warranty.

40.

WHEREFORE, Plaintiff prays for judgment as hereinafter set forth.

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#### [Breach of Express Warranty]

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Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation contained in Paragraphs 1-40, inclusive, of this Complaint.

42.

Defendants, and each of them, expressly warranted to Plaintiff and/or her authorized agents or sales representatives, in publications, and other communications intended for medical patients, and the general public, that AVANDIA was safe, effective, fit and proper for its intended use.

43.

Plaintiff MARTHA ARRIOLA and Plaintiff's physicians reasonably relied upon the skill and judgment of Defendants, and each of them, and upon said express warranty, in using the aforesaid product. The warranty and representations were untrue in that the product caused severe injury to Plaintiff MARTHA ARRIOLA and was unsafe and, therefore, unsuited for the use in which it was intended and caused Plaintiff MARTHA ARRIOLA to sustain damages and injuries herein alleged.

44

As soon as the true nature of the product, and the fact that the warranty and representations were false, were ascertained, said Defendants, and each of them, had ample and sufficient notice of the breach of said warranty.

45.

WHEREFORE, Plaintiff prays for judgment as hereinafter set forth.

#### FIFTH CAUSE OF ACTION

[Fraud]

46

Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation contained in Paragraphs 1-45, inclusive, of this Complaint.

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47.

Defendants, and each of them, falsely and fraudulently represented to Plaintiff MARTHA ARRIOLA, her physicians, and to members of the general public that the aforesaid product was safe, effective, reliable, consistent, and better than the other similar products due to its ability to increase insulin sensitivity without causing serious harm when used in the manner intended by the manufacturer. The representations by said Defendants, and each of them, were in fact, false. The true facts include, but are not limited to the fact that the aforesaid product was not safe to be used and was, in fact, dangerous to the health and body of Plaintiff MARTHA ARRIOLA.

When the Defendants, and each of them, made these representations, they knew that they were false. Defendants, and each of them, made said representations with the intent to defraud and deceive Plaintiff MARTHA ARRIOLA, with the intent to induce plaintiff to act in the manner herein alleged, that is to use the aforementioned product for increasing insulin sensitivity...

At the time Defendants, and each of them, made the aforesaid representations and Plaintiff MARTHA ARRIOLA took the actions herein alleged, Plaintiff and her physicians were ignorant of the falsity of these representations and reasonably believed them to be true. In reliance upon said representations, Plaintiff was induced to, and did, use the aforesaid product as herein described. If Plaintiff MARTHA ARRIOLA had known the actual facts, she would not have taken such action. The reliance of Plaintiff and her physicians upon Defendants', and each of their, representations were justified because said representations were made by individuals and entities who appeared to be in a position to know the true facts.

50.

As a result of Defendants', and each of them, fraud and deceit, Plaintiff was caused to sustain the herein described injuries and damages.

51.

In doing the acts herein alleged, the Defendants, and each of them, acted with oppression, fraud, and malice, and Plaintiff is therefore entitled to punitive damages to deter Defendants, and each of them, and others from engaging in similar conduct in the future. Said wrongful conduct was done with advance knowledge, authorization and/or ratification of an officer, director and/or managing agent of Defendants.

52.

WHEREFORE, Plaintiff prays for judgment as hereinafter set forth.

#### SIXTH CLAIM FOR RELIEF

[Fraud by Concealment]

53.

Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation contained in Paragraphs 1-52, inclusive, of this Complaint.

At all times mentioned herein, Defendants, and each of them, had the duty and obligation to disclose to Plaintiff and to her physicians, the true facts concerning the aforesaid product, AVANDIA, that is, that said product was dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users including serious and permanent injuries to the heart. Defendants, and each of them, made the affirmative representations as set forth above to Plaintiff and her physicians and the general public prior to the date AVANDIA was ingested by Plaintiff MARTHA ARRIOLA, while concealing material facts.

At all times herein mentioned, Defendants, and each of them, willfully, and maliciously concealed facts as set forth above from Plaintiff and her physicians, and therefore, Plaintiff, with the intent to defraud as herein alleged.

56.

At all times herein mentioned, neither Plaintiff nor her physicians were

COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL

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aware of the facts set forth above, and had they been aware of said facts, she would not have acted as she did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized the AVANDIA for increasing insulin sensitivity. Defendants', and each of their, representations were a substantial factor in Plaintiff utilizing AVANDIA for increasing insulin sensitivity.

As a result of the concealment of the facts set forth above, Plaintiff sustained injuries as hereinafter set forth.

In doing the action herein alleged, Defendants, and each of them, acted with. oppression, fraud, and malice and Plaintiff is therefore entitled to punitive damages in an amount reasonably related to Plaintiff's actual damages, and to Defendant's wealth, and sufficiently large to be an example to others, and to deter these Defendants, and each of them, and others from engaging in similar conduct in the future.

59.

WHEREFORE, Plaintiff prays for judgment as hereinafter set forth.

#### SEVENTH CAUSE OF ACTION

[Negligent Misrepresentation]

Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation contained in Paragraphs 1-59, inclusive, of this Complaint.

At all relevant times herein, Defendants, and each of them, represented to Plaintiff MARTHA ARRIOLA and her physicians that the AVANDIA was safe to use to increase insulin sensitivity knowing that the AVANDIA was defective in causing injuries described herein.

The Defendants, and each of them, made the aforesaid representations with

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no reasonable ground for believing them to be true when Defendants', and each of their, own data showed the AVANDIA to be defective and dangerous when used in the intended manner.

63

The aforesaid representations were made to the physicians prescribing AVANDIA prior to the date it was prescribed to Plaintiff and her physicians with the intent that Plaintiff and her physicians would rely upon such misrepresentations about the safety and efficacy of AVANDIA. Plaintiff and her physicians did reasonably rely upon such representations that the aforesaid product was safe for use to aid in the treatment of increasing insulin sensitivity.

64

The representations by said Defendants, and each of them, to Plaintiff were false, and thereby caused Plaintiff's injuries described herein.

65.

WHEREFORE, Plaintiff prays for judgment as hereinafter set forth.

#### **EIGHTH CAUSE OF ACTION**

[Violations of the Consumer Legal Remedies Act, Civil Code §1750, et seq.]

66.

Plaintiff MARTHA ARRIOLA hereby incorporates by reference, as if fully set forth herein, each and every allegation contained in Paragraphs 1-84, inclusive, of this Complaint.

67.

This Cause of Action is brought pursuant to the Consumer Legal Remedies Act ("CLRA"), California Civil Code §1750, et seq.

68.

The policies, acts, and practices described above were intended to result in the sale of AVANDIA to Plaintiff MARTHA ARRIOLA and the general public. These actions violated, and continued to violate, the CLRA in at least the following respects:

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	(a)	In violation of §17	770(a)(2), misrepresent	ing the source, sp	onsorship
ipproval, or	certificati	on of AVANDIA;			

- (b) In violation of §1770(a)(5), representing that the AVANDIA has sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that it does not have;
- (c) In violation of §1770(a)(7), representing that the AVANDIA is of a particular standard, quality, or grade;

69.

In compliance with the CLRA provision in California Civil Code §1782, Plaintiff have given written notice to each Defendant named in this Complaint of his intention to file an action for damages under Civil Code §1750, et seq.

70.

Plaintiff notified Defendants, and Defendants have failed, within 30 days after receipt of the Civil Code §1782 notice, to adequately respond to Plaintiff's demand to correct, repair, replace, or otherwise rectify the wrongful conduct described above. Per Civil Code §1782(b), this action for damages under Civil Code §1780 may be maintained because Defendants, and each of them, failed to give, or agree to give within a reasonable time, any appropriate correction, repair, replacement, or other remedy to Plaintiff within 30 days after receipt of the §1782 notice.

71.

Plaintiff seeks actual and punitive damages for violations of the CLRA. In addition, Plaintiff is entitled to, pursuant to California Civil Code §1780(a)(2), an order enjoining the above-described wrongful acts and practices, restitution to Plaintiff MARTHA ARRIOLA, costs and attorneys' fees, and any other relief deemed appropriate and proper by the Court and under Civil Code §1780.

#### PRAYER FOR RELIEF

72.

Plaintiff prays that a judgment be entered in favor of Plaintiff in such

proof;

aggregate sum as will fairly and reasonably compensate Plaintiff for damages arising out of the conduct of Defendants, and each of them, as described herein. The conduct of Defendants, and each of them, as alleged herein, was a direct, proximate and producing cause of the damages to Plaintiff and the following general and specific damages:

- For general damages in a sum within the jurisdiction of this Court;
- For medical, hospital, and incidental expenses, according to proof; 2.
- For loss of earnings and for loss of earning capacity, according to 3.
- For punitive or exemplary damages; 4.
- For such other relief as the Court deems just and proper. **5**.

DATED: March 17, 2008.

HERSH & HERSH A Professional Corporation

Attorneys for Plaintiff

**EXHIBIT B** 

DONALD F. ZIMMER, JR. (State Bar No. 112279) KRISTA L. COSNER (State Bar No. 213338) DRINKER BIDDLE & REATH LLP 50 Fremont Street, 20<sup>th</sup> Floor San Francisco, California 94105 Telephone: (415) 591-7500 Facsimile: (415) 591-7510 2 3 MAR 2 1 2008 5 GORDON PARKLI, Clark Attorneys for Defendant SMITHKLINE BEECHAM CORPORATION dba GLAXOSMITHKLINE 6 7 8 SUPERIOR COURT OF THE STATE OF CALIFORNIA 9 FOR THE COUNTY OF SAN FRANCISCO 10 MARTHA ARRIOLA, Case No. CGC-08-473387 ANSWER TO COMPLAINT BY DEFENDANT SMITHKLINE BEECHAM CORPORATION dba Plaintiff, 12 13 GLAXOSMITHKLINE SMITHKLINE BEECHAM CORPORATION dba GLAXOSMITHKLINE; McKESSON 14 15 CORPORATION; and DOES 1 through 15, inclusive, 16 Defendants. 17 18 19 INTRODUCTION 20 Defendant SMITHKLINE BEECHAM CORPORATION dba 21 GLAXOSMITHKLINE ("GSK") by and through counsel, hereby responds to the 22 allegations set forth by MARTHA ARRIOLA ("Plaintiff") in her Complaint for Damages .23 (the "Complaint") as follows: 24 GENERAL DENIAL 25 By virtue of the provisions of California Code of Civil Procedure §431.30, 26 Defendant generally denies each and every allegation in the unverified Complaint that 27 relates to or is directed to Defendant or any of its alleged agents, servants or employees: Defendant further denies that Plaintiff has been damaged to any extent or amount or is MKER BIDDLE & REATH LLP

ANSWER TO COMPLAINT BY DEFENDANT GSK

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entitled to any relief whatsoever from Defendant.

Defendant additionally denies that there is any law, fact, theory or contractual or legal relationship under which Plaintiff is entitled to damages in any amount by this answering Defendant.

Defendant further alleges the following affirmative defenses to Plaintiff's : Complaint:

#### AFFIRMATIVE DEFENSES

#### FIRST AFFIRMATIVE DEFENSE

(Improper Venue)

Venue is improper.

#### SECOND AFFIRMATIVE DEFENSE

(Insufficiency of Process and Insufficiency of Service of Process)

Process and service of process are insufficient under California law.

#### THIRD AFFIRMATIVE DEFENSE

(Failure to State a Claim)

Plaintiff's Complaint fails to state a claim upon which relief may be granted.

#### FOURTH AFFIRMATIVE DEFENSE

#### (Preemption/Primary Jurisdiction)

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction, in that the FDA is charged under the law with regulating prescription drugs, including Avandia®, and is specifically charged with determining the content of the warnings and labeling for prescription drugs. The granting of the relief prayed for in the Plaintiff's Complaint would impede, impair, frustrate or burden the effectiveness of such federal law and would violate the Supremacy Clause (Art. VI, cl. 2) of the United States Constitution.

#### FIFTH AFFIRMATIVE DEFENSE

(Statute of Limitations/Repose)

Discovery may show that Plaintiff's claims are barred, in whole or in part, by

applicable statutes of limitations, statutes of repose, the doctrine of laches and/or as a result of the failure to allege and/or comply with conditions precedent to applicable periods of limitations and repose.

#### SIXTH AFFIRMATIVE DEFENSE

(Assumption of Risk)

Plaintiff knowingly and voluntarily assumed any and all risks as to matters alleged in the Complaint, and such assumption of the risk bars in whole or in part the damages Plaintiff seeks to recover herein.

#### SEVENTH AFFIRMATIVE DEFENSE

(Contributory/Comparative Negligence)

At all times mentioned herein, Plaintiff was negligent, careless, and at fault and conducted herself so as to contribute substantially to any alleged risk of injuries and damages. Said negligence, carelessness and fault of Plaintiff bars in whole or in part the damages which Plaintiff seeks to recover herein.

#### EIGHTH AFFIRMATIVE DEFENSE

(Equitable Defenses)

Plaintiff's claims are barred by the doctrine of laches, estoppel, waiver, unclean hands and/or failure to preserve evidence.

#### NINTH AFFIRMATIVE DEFENSE

(Improper Party Defendant)

McKesson is not a proper party defendant to this action. McKesson was not involved with Avandia<sup>®</sup>, a product of GSK.

#### TENTH AFFIRMATIVE DEFENSE

(Intervening, Superseding Cause)

The damages allegedly sustained by Plaintiff, if any, were not legally caused by Defendant, but instead were legally caused by intervening and superseding causes or circumstances.

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#### **ELEVENTH AFFIRMATIVE DEFENSE**

#### (Pre-existing Condition or Idiosyncratic Reaction)

The risk of injuries, if any, resulted from a pre-existing and/or related medical condition and/or idiosyncratic reaction and not from any act or omission by or on behalf of Defendant.

#### TWELFTH AFFIRMATIVE DEFENSE

#### (Fault of Others)

Plaintiff's alleged injuries, losses, or damages, if any, were caused by the actions negligence, carelessness, fault, strict liability, or omissions of third parties for which Defendant has no control or responsibility.

#### THIRTEENTH AFFIRMATIVE DEFENSE

#### (Learned Intermediary)

Plaintiff's claims are barred in whole or in part by the learned-intermediary doctrine.

#### FOURTEENTH AFFIRMATIVE DEFENSE

#### (Compliance with FDA Regulations)

At all times relevant, the product was in accordance with and pursuant to all applicable statutes and regulations, including those of the Food and Drug Administration.

#### FIFTEENTH AFFIRMATIVE DEFENSE

#### (Immunity for Prescription Drugs and Medical Devices)

The Complaint and each cause of action thereof are barred by the doctrine of immunity for prescription drugs and medical devices, by the Commerce Clause, Article I, Section 8, of the Constitution of the United States as an undue burden upon interstate commerce and/or by the preemption doctrine in that Plaintiff has asserted claims for relief which, if granted, would constitute an impermissible burden by this court on federal laws, regulations and policy relating to the development and marketing of prescription drugs and medical devices in violation of the Supremacy Clause, Article IV, Clause 2 of the Constitution of the United States.

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# SIXTEENTH AFFIRMATIVE DEFENSE

#### (Restatements of Torts)

Defendant affirmatively pleads the application of the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and/or the Restatement (Third) of Torts: Products Liability §§ 2, 4 and 6 and comments thereto. Adequate warnings and complete warnings were provided to Plaintiff's prescribing physician, and therefore, the product was not defective or unreasonably dangerous.

### SEVENTEENTH AFFIRMATIVE DEFENSE

#### (State of the Art)

At all times material hereto, Defendant's conduct and GSK's product, Avandia®, conformed to the state of the art.

#### EIGHTEENTH AFFIRMATIVE DEFENSE

#### (Limitations on Punitive Damages)

With respect to Plaintiff's demand for punitive or exemplary damages, Defendant specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damages awards, including but not limited to, those standards of limitation which arose in BMW of North America v. Gore, 517 U.S. 559 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001), and State Farm Mutual Automobile Ins. Co. v. Campbell, 538 U.S. 408 (2003), and Philip Morris USA v. Williams, 127 S.Ct. 1057 (2007).

# NINETEENTH AFFIRMATIVE DEFENSE

### (Punitive and Exemplary Damages Not Proper)

Plaintiff's claim for punitive damages violates, and it is therefore barred by, the Fourth, Fifth, Sixth, Eighth, and Fourteenth Amendments to the Constitution of the United States of America on grounds including the following:

it is a violation of the Due Process and Equal Protection Clauses of the a. Fourteenth Amendment to the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiff satisfying a burden

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of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

- b. the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple Defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment to the United States Constitution;
- c. the procedures pursuant to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against defendant, which thereby violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution;
- d. the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment to the United States Constitution;
- e. the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution;
- f. the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment to the United States Constitution;
- g. the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment to the United States Constitution;
- h. the award of punitive damages to plaintiff in this action would constitute a deprivation of property without due process of law; and

i. the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

#### TWENTIETH AFFIRMATIVE DEFENSE

(No Failure to Warn)

Defendant at all times discharged any duty to warn through appropriate and adequate warnings in accordance with federal statutes and regulations and with the then-existing states of medical and scientific knowledge.

#### TWENTY-FIRST AFFIRMATIVE DEFENSE

(Failure to Plead Fraud with Particularity)

Plaintiff has failed to plead a cause of action for fraud as she has not set forth allegations of fraud with the requisite particularity.

### TWENTY-SECOND AFFIRMATIVE DEFENSE

(Product Safety)

At all times relevant, Avandia® was not unreasonably dangerous or defective.

# TWENTY-THIRD AFFIRMATIVE DEFENSE

(Failure to Join Necessary Party)

Complete relief cannot be accorded among those already parties and, in the alternative, the disposition of this action without the presence of additional, unnamed persons may result in Defendant being subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations.

# TWENTY-FOURTH AFFIRMATIVE DEFENSE

(Set Off)

Defendant pleads as a set off any monies received by Plaintiff for injuries or damages attributed to the subject incident, including, but not limited to, any insurance proceeds.

### TWENTY-FIFTH AFFIRMATIVE DEFENSE

(Lack of Causation)

Defendant asserts that its conduct did not cause, proximately cause, solely cause,

28 Drinker Broce & Reath LP 50 Fremont Street, 20th Floo San Francisco, CA 94103

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or solely proximately cause the injuries and/or damages alleged by Plaintiff.

#### TWENTY-SIXTH AFFIRMATIVE DEFENSE

(Good Faith)

Defendant's acts were at all times done in good faith and without malice, with respect to each and every purported cause of action in Plaintiff's Complaint.

#### TWENTY-SEVENTH AFFIRMATIVE DEFENSE

(Unintentional Acts)

Any alleged act or omission by Defendant concerning the manufacture, distribution, marketing, and/or sale of Avandia® and/or any other conduct in relation thereto was at all times unintentional and resulted from a bona fide error notwithstanding the use of reasonable procedures adopted to avoid any such error, and Defendant made an appropriate correction, repair, replacement, or remedy to the goods once notified of the error.

### TWENTY-EIGHTH AFFIRMATIVE DEFENSE

(Conformity with Medical Knowledge)

With respect to each and every purported cause of action in Plaintiff's Complaint, Defendant alleges that the methods, standards, and techniques in the preparation of GSK's product, Avandia®, were and are in conformity with the generally recognized state of medical knowledge, common and accepted procedure in the medical field, and state of the art at the time of their preparation.

### TWENTY-NINTH AFFIRMATIVE DEFENSE

(Equitable Indemnity)

In the event Defendant is held liable to Plaintiff, which liability is expressly denied, and any other entity is also found liable, Defendant is entitled to a percentage contribution of the total liability from said entity in accordance with principles of equitable indemnity and comparative contribution.

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# THIRTIETH AFFIRMATIVE DEFENSI

(Proposition 51)

The liability of Defendant, if any, for Plaintiff's non-economic loss must be apportioned in accordance with the provisions of California Civil Code § 1431.2 ("Proposition 51").

#### THIRTY-FIRST AFFIRMATIVE DEFENSE

(Failure to Mitigate Damages)

Plaintiff's damages, if any, are barred in whole or in part by Plaintiff's failure to mitigate such damages.

#### THIRTY-SECOND AFFIRMATIVE DEFENS

(No Notice of Breach of Warranty)

Plaintiff failed to give notice of any alleged breach of warranty.

#### THIRTY-THIRD AFFIRMATIVE DEFENSE

(Disclaimer of Warranty)

Defendant alleges that any and all warranties that may form a basis for Plaintiff's claims for relief were adequately disclaimed as stated by Defendant.

### THIRTY-FOURTH AFFIRMATIVE DEFENSE

(No Reliance on Warranties)

Defendant denies that Plaintiff relied on any warranties alleged in the Complaint.

### THIRTY-FIFTH AFFIRMATIVE DEFENSE

(Unavoidable Circumstances)

The alleged injuries and/or damages of Plaintiff, if any, were the result of unavoidable circumstances that could not have been prevented by anyone.

### THIRTY-SIXTH AFFIRMATIVE DEFENSE

(Misuse)

If Plaintiff sustained injuries or risk of injuries in this action, which allegations are expressly denied, the injuries or risk of injuries were solely caused by and attributable to the unintended, unreasonable, and improper use which Plaintiff made of the product.

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#### THIRTY-SEVENTH AFFIRMATIVE DEFENSE

(No Strict Liability for Prescription Drugs).

The strict liability causes of action of Plaintiff's Complaint are subject to the limitations placed upon the doctrine of strict product liability for a purported design defect as set forth in Brown v. Superior Court, 44 Cal. 3d. 1049 (1988) and its progeny.

#### THIRTY-EIGHTH AFFIRMATIVE DEFENSE

(Buckman v. Plaintiff's Legal Community)

To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman v. Plaintiff's Legal Community, 531 U.S. 341 (2001).

#### THIRTY-NINTH AFFIRMATIVE DEFENSE

(Standing)

Plaintiff lacks standing to bring some or all of the claims alleged in the Complaint.

#### FORTIETH AFFIRMATIVE DEFENSE

(Unconstitutional Claims)

Defendant alleges that granting Plaintiff's requested relief under the Consumers Legal Remedies Act, California Civil Code § 1750 et seq. ("CLRA"), would violate Defendant's rights under the United States and California constitutions.

### FORTY-FIRST AFFIRMATIVE DEFENSE

(Adequate Remedy at Law)

Plaintiff's causes of action under the CLRA, California Civil Code §1750, et seq., and the remedies sought thereunder, are barred because there is an adequate remedy at law.:

# FORTY-SECOND AFFIRMATIVE DEFENSE

(Failure to Give Preliminary Notice)

Plaintiff has failed to comply with the CLRA notice requirements of California Civil Code § 1782.

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#### FORTY-THIRD AFFIRMATIVE DEFENSE

#### (Choice of Law)

- (a) Plaintiff's claims are not governed by the laws of the State of California.
- (b) Defendant is entitled to the benefit of all defenses and presumptions contained in, or arising from, any rule of law or statute of any other state whose substantive law might control the action.

# FORTY-FOURTH AFFIRMATIVE DEFENSE

#### (Other Defenses)

Defendant hereby gives notice that it intends to rely upon any other affirmative defenses pled by any other defendant and not pled by itself in this action to the extent they do not conflict with Defendant's own affirmative defenses. Defendant reserves its right to amend its Answer to assert any additional defenses and matters in avoidance that may be disclosed during the course of additional investigation and discovery.

#### JURY DEMAND

Defendant requests a trial by jury of this matter.

#### PRAYER FOR RELIEF

## WHEREFORE, Defendant prays:

- That the Complaint be dismissed with prejudice as to the answering
   Defendant and that judgment be entered in its favor;
  - 2. For costs of suit incurred herein;
  - 3. And for such other relief as the Court may deem just and appropriate.

Dated: March 2, 2008

DRINKER BIDDLE & REATH LLP

DONALD F. ZIMMER, JR. KRISTA L. COSNER

Attorneys for Defendant SMITHKLINE BEECHAM CORPORATION dba GLAXOSMITHKLINE

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CERTIFICATE OF SERVICE 2 I, LEE ANN L. ALLDRIDGE, declare that: 3 I am at least 18 years of age, and not a party to the above-entitled action. My 4 business address is 50 Fremont Street, 20th Floor, San Francisco, California 94105, 5 Telephone: (415) 591-7500. 6 On March 21, 2008, I caused to be served the following document(s): 7 ANSWER TO COMPLAINT BY DEFENDANT SMITHKLINE BEECHAM CORPORATION dba GLAXOSMITHKLINE 8 by enclosing a true copy of (each of) said document(s) in (an) envelope(s), addressed as ġ follows: 10 Ⅵ. BY MAIL: I am readily familiar with the business' practice for collection and processing of correspondence for mailing with the United States Postal Service. I know that the correspondence is deposed with the United States Postal Service on 11 the same day this declaration was executed in the ordinary course of business. I . 12 know that the envelope was sealed, and with postage thereon fully prepaid, placed for collection and mailing on this date, following ordinary business practices, in the United States mail at San Francisco, California. 13 BY PERSONAL SERVICE: I caused such envelopes to be delivered by a messenger service by hand to the address(es) listed below: 15 BY OVERNIGHT DELIVERY: I enclosed a true copy of said document(s) in a Federal Express envelope, addressed as follows: 16 17 BY FACSIMILE: I caused such documents to be transmitted by facsimile transmission and mail as indicated above. 18 Nancy Hersh 19 Mark E. Burton, Jr. Rachel Abrams 20 Cynthia Brown HERSH & HERSH 21 601 Van Ness Avenue, Suite 2080 San Francisco, CA 94102 22 Telephone: (415) 441-5544 23 I declare under penalty of perjury under the laws of the State of California that the 24 above is true and correct. Executed on March 21, 2008 at San Francisco, California. 25 CLULLA CULLA G LEE ANN L. ALLDRIDGE 26 27 DRINGER RIOTHE & REATHELP 50 Fremont Street, 20th Floo San Francisco, CA 94105 CERTIFICATE OF SERVICE

**EXHIBIT C** 

MDL 1871

UNITED STATES JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

7:23 am, Oct 16, 2007

FILED CLERK'S OFFICE

UNITED STATES JUDICIAL PANEL MULTIDISTRICT LITIGATION

IN RE: AVANDIA MARKETING, SALES PRACTICES. AND PRODUCTS LIABILITY LITIGATION

> Sharon Ann Dabon v. GlaxoSmithKline, Inc., E.D. Louisiana, C.A. No. 2:07-3041 Celenio Cruz-Santana v. GlaxoSmithKline, PLC, et al., D. Puerto Rico, C.A. No. 3:07-1461

MDL No. 1871

#### TRANSFER ORDER

Before the entire Panel'; Plaintiff in the action pending in the Eastern District of Louisiana, has moved, pursuant to 28 U.S.C. § 1407, to centralize this litigation in the District of Puerto Rico or, alternatively, in the Eastern District of Louisiana, This litigation currently consists of moving plaintiff's action and one action pending in the District of Puerto Rico. Plaintiff in the latter action supports centralization in the District of Puerto Rico. Plaintiffs in potential tag-along actions pending in the Central District of California, the Southern District of Florida, the District of New Jersey, the Southern District of New York, and the District of Puerte Rico have submitted responses in support of centralization. These plaintiffs suggest a variety of fora for transferce district, including the Southern District of Florida (favored by plaintiffs in the action pending in that district), the District of New Jersey (favored by plaintiff in the action pending in that district, as well as plaintiff in the Central District of California action), the Southern District of New York (favored by plaintiffs in eight actions pending in that district), and the District of Puerto Rico (favored by plaintiffs in the action pending in that district). Responding defendant SmithKlineBeecham Corp. d/b/a GlaxoSmithKline (GSK) initially opposed the Section 1407 motion, but now supports centralization in the Eastern District of Pennsylvania.

OFFICIAL FILE COPY

IMAGED OCT 1 6 2007

Judge Heyburn took no part in the disposition of this matter.

The Panel has been notified of 28 additional related actions pending in the Western District of Arkansas, the Central District of California (two actions), the Southern District of Florida (two actions), the Southern District of Illinois, the Southern District of Indiana, the Eastern District of Louisiana, the District of New Jersey, the Eastern District of New York, the Southern District of New York (ten actions), the Northern District of Ohio, the Eastern District of Oklahoma, the Eastern District of Pennsylvania, the District of Puerto Rico, the Eastern District of Tennessee, the Western District of Tennessee, and the Eastern District of Texas (two actions). These actions and any other related actions will be treated as potential tag-along actions. See Rules 7.4 and 7.5, R.P.I.P.M.L., 199 F.R.D. 425, 435-36 (2001).

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On the basis of the papers filed and hearing session held, we find that these actions involve common questions of fact, and that centralization under Section 1407 in the Eastern District of Pennsylvania will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. Both actions arise from allegations that certain diabetes drugs manufactured by GSK - Avandia and/or two sister drugs containing Avandia (Avandamet and Avandaryl) - cause an increased risk of heart attack and other physical injury, and that GSK failed to provide adequate warnings concerning that risk. Centralization under Section 1407 will eliminate duplicative discovery, avoid inconsistent pretrial rulings, and conserve the resources of the parties, their counsel and the judiciary.

We are also persuaded that the Eastern District of Pennsylvania is an appropriate transferee district for precial proceedings in this litigation. GSK's principal place of business is located in that district, and thus many witnesses and documents relevant to the litigation are likely to be found there. In addition, one of the potential tag-along actions was commenced in the Eastern District of Pennsylvania.

IT IS THEREFORE ORDERED that, pursuant to 28 U.S.C. § 1407, the two actions are transferred to the Eastern District of Pennsylvania and, with the consent of that court, assigned to the Honorable Cynthia M. Rufe for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION

D. Loweli Jensen Acting Chairman

John G. Heyburn II, Chairman J. Frederick Motz Robert L. Miller, Jr.

David R. Hansen

Kathryn H. Vratil Anthony J. Scirica

**EXHIBIT D** 

Case 2:08-at-00278 Document 3-3 Filed 03/10/2008 Page 20 of 21 1 DONALD F. ZIMMER, JR. (State Bar No. 112279) KRISTA L. COSNER (State Bar No. 213338) DRINKER BIDDLE & REATH LLP 50 Fremont Street, 20th Floor San Francisco, California 94105 Telephone: (415) 591-7500 Facsimile: (415) 591-7510 2 3 4 5 Attorneys for Defendants SMITHKLINE BEECHAM CORPORATION dba б GLAXOSMITHKLINE and McKESSON CORPORATION 8 UNITED STATES DISTRICT COURT 9 EASTERN DISTRICT OF CALIFORNIA 10 11 F.C. MITCHELL and MITSUKO Case No. MITCHELL and MITSUKO
MITCHELL, husband and wife; MARY
RYON and JAMES RYON, wife and
husband; CARL HOUSTON and ALICE
HOUSTON, husband and wife; JOSEPH
WOODS, SR. and BILLIE WOODS,
husband and wife; DONALD WINTERS
and KELLEY WINTERS, husband and
wife; RAY STOCK, as surviving statutory
beneficiary for the wrongful death of 12 DECLARATION OF GREG YONKO IN 13 SUPPORT OF NOTICE OF REMOVAL AND REMOVAL ACTION, UNDER 28 U.S.C. § 1441(B) (DIVERSITY) and 28 U.S.C. § 1441(C) (FEDERAL QUESTION) OF DEFENDANT SMITHKLINE BEECHAM 14 15 16 beneficiary for the wrongful death of JOLENE STOCK; WILMA POLLARD, as CORPORATION dba GLAXOSMITHKLINE 17 surviving statutory beneficiary for the wrongful death of KENNETH POLLARD, 18 Plaintiffs, 19 20 GLAXOSMITHKLINE, a Pennsylvania 21 corporation; MCKESSON CORPORATION, a California Corporation; 22 and DOES 1-50, 23 Defendants. 24 25 I, GREG YONKO, declare: 26 I am Senior Vice President - Purchasing for McKesson Corporation ("McKesson"), and make this declaration in support of the Notice of Removal and 28 Removal Action of defendant SmithKline Beecham Corporation dba GlaxoSmithKline Drinker Biddle & Reath LLP 50 Fremont Street, 20th Floor San Francisco, CA 94105 DECLARATION OF GREG YONKO IN SUPPORT OF REMOVAL CASE NO.

Document 3-3 Filed 03/10/2008 Page 21 of 21 Case 2:08-at-00278

("GSK") based on my personal knowledge.

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- I have been in my current position since 1997, and have been employed by McKesson for over 25 years. As Vice President of Purchasing, I am responsible for purchasing prescription and non-prescription branded product management and investment purchasing.
- 3. McKesson was and is a Delaware corporation, with its principal place of business in San Francisco, California.
- McKesson was served with the Summons and Complaint in this action on February 11, 2008.
  - 5. McKesson consents to the removal of this action.
- 6. McKesson is a wholesale distributor of pharmaceuticals, over-the-counter and health and beauty products to chains, independent pharmacy customers and hospitals. As a wholesale distributor, McKesson distributes products manufactured by others. As to Avandia®, McKesson does not manufacture, produce, process, test, encapsulate, label, or package, these products, nor does it make any representations or warranties as to the product's safety or efficacy.
- McKesson distributed Avandia®, manufactured by GSK, along with many 7. other products of other pharmaceutical companies, to certain drug stores, pharmacies, health care facilities and hospitals throughout the United States. As stated above, McKesson did not manufacture, produce, process, test, encapsulate, label, or package Avandia®, but only delivered the unopened boxes that contained the drug.
- McKesson is one of many suppliers who could have supplied Avandia® to the numerous pharmacies throughout the United States.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct, and this declaration was executed on March 5. 2008 in San Francisco, California COR. FOREST

Dronker Biodle & Reathlup 50 Fremoni Street, 20th Floor

encisco, CA 94105

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